OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6717

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
200 C Street, S.W.
WASHINGTON, DC 20515

CONCERNING

Novel Antibodies against Influenza Virus, Emerging, re-Emerging, and pre-Emerging pathogens

Modification No. 0006

Date: March 20, 2020

PR No.: OS 206444 $18,693,213; OS 233799 $19,274,081; OS234612 $278,812; OS 253326 $5,751,859; OS256115 $92,984,806

Total Amount of the Agreement: $171,228,467 (Changed)

Total Estimated Government Funding of the Agreement: $136,982,771 (Changed)
Total Estimated Recipient Funding of the Agreement: $34,245,693 (Changed)
Funds Obligated: $136,982,771 (Changed)
Period of Performance: September 30, 2017 through March 31, 2026 (Changed)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027
(b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 199TWLN
(b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994047
(b) (4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994044
(b) (4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027 (b) (4) (CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 199TWLN (b) (4) (CLIN 0003)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 199TWRY (b) (4) and $ (b) (4) CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 1992019 (b) (4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class: 25106; Appropriation Yr: 2020, CAN: 1992020 (b) (4) CLIN 0001 and (b) (4) CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25103; Appropriation Yr: 2020, CAN: 199COV2 (b) (4) CLIN 0003; (b) (4) CLIN 0004; (b) (4) CLIN 0005 and (b) (4) CLIN 0006)

PURPOSE: The purpose of this modification is to increase funds to CLIN 0003 and exercise CLINs 0004 (Option 3), 0005 (Option 4) and CLIN 0006 (Option 5). Option 3 work will include GMP manufacturing, Option 4 work will include first-in-human clinical studies and Option 5 work will be the SARS-2 IL6 activities, (2) Revise the period of performance, (3) add two deliverables, (4) Replace Attachment 1: SOW revision dated March 20, 2020 and (5) Revise Attachment 6 (Requisition Table) reflecting the associated requisitions.

Beginning with the effective date of this modification, the Government and Other Transaction Agreement holder mutually agree as follows:

1. Agreement No.:
   HHSO100201700020C Line Items and corresponding values:

   Funding for this OTA is revised as follows:

Line Item	Recipient Cost-Share	Government Cost-Share	Total Estimated Cost	Total Government Funds Obligated to Date
0001 - Base Period	(b) (4)			$12,118,721
0001-MERS				$164,378
0001-FILO				$278,812
0002 - Option 1				$22,947,315
0003 - Option 2				$16,977,483
0004 - Option 3				$59,349,187
0005 - Option 4				$ 8,778,490
0006 - Option 5				$14,233,381
0006 - Option 5				$2,135,007
*-Contingency fee	(b) (4)		Total:	$136,982,773

Note:

(i) Internal Expenses. Internal expenses will be determined based on actual labor hours for the activities performed, multiplied by a single, fully-burdened FTE rate not subject to true-up, calculated for the Research & Development organization which will be working on the programs under this Agreement. This rate will be adjusted annually based on the CPI adjustment methodology outlined in the final cost proposal. The Contracting Officer will request documents supporting adjustments in the CPI.

(ii) External (Subrecipient or Affiliates) Expenses. External expenses will be billed based on actual third-party charges submitted to Regeneron.

(iii) Drug Supply. Drug supply manufactured at a Regeneron facility will be billed based on a fully-allocated cost methodology which includes direct variable, direct fixed and indirect cost allocations (See the 9/14/17 proposal). Drug manufactured by a third party contract manufacturer will be billed based on actual third party charges submitted to Regeneron.

(iv) G&A. G&A expenses will be billed for external expenses and drug supply based on a set rate not subject to true-up. A negotiated rate agreement or rate documentation shall be provided in the subrecipient agreement.

2. Under Article II PERIOD OF PERFORMANCE, delete and replace as follows:

Line Item	Description of Services	Period of Performance
0001	Base Period-Generation and isolation and characterization of leads against PEPs, Eps, or REPs or host target(s), and generation of (humanized) mouse model for PEP, EP or REP	September 25, 2017-June 30, 2021
0002	Option 1-PMPD Production and in-vivo testing of lead therapies	September 25, 2017-June 30, 2022
0003	Option 2-Toxicology activities	September 25, 2017-May 31, 2021
0004	Option 3-IND enabling activities	March 23, 2020-May 31, 2026
0005	Option 4-Clinical Study	March 23, 2020-March 31, 2026
0006	Option 5-Additional Clinical Study	March 16, 2020-March 31, 2026

3. Under **ATTACHMENT 2, REPORTING REQUIREMENTS**, add three deliverables as follows:

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the COR, CS, and CO.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01.6	Daily check in with project staff for COVID-19 Contract	Upon request of the Government relating to COVID-19, the Contractor shall participate in regular updates with the project staff (via teleconference or email). Contractor will respond in a timely fashion (if reasonable and practicable under the circumstances, within the same day as the request).	No agenda will be required for the meeting No meeting minutes are required

		The parties will agree on the frequency and content for these updates on the COVID-19 programs. The parties expect the nature, content and frequency to change from time to time, depending on the circumstances. The updates will address the content reasonably requested by BARDA and in the possession of, and reasonably accessible to, Regeneron, including key cost, schedule and technical updates. Updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats. Updates may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	Contractor will provide updates verbally, in bulleted emails or other mutually agreed formats
02.8	Product Development Source Material and Manufacturing Report for COVID-19 Programs	For COVID-19 programs, the Contractor shall submit a spreadsheet regarding critical project materials. The form and content of the spreadsheet will be similar to past updates provided by Contractor with respect to its MERS antibodies. The parties acknowledge that, for SARS-CoV-2 antibodies, Regeneron will provide this information when it becomes available after finalizing the manufacturing process.	• Contractor will submit Product Development Source Material Report Within 30 business days of contract award Within 30 business days of substantive changes are made to sources and/or materials The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission If corrective action is recommended, Contractor will respond to such concerns in writing

4. Attached are the following revised documents:

   1) Delete and replace Attachment 1 – Revised Statement of Work (SOW) dated March 20, 2020 18 pages).
   2) Delete and replace Attachment 6 - Requisition Table

All other terms and conditions remain the same.

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS SECRETARY
FOR PREPAREDNESS AND RESPONSE

Carl A. Newman -S

Digitally signed by Carl A. Newman -S
Date: 2020.03.21 12:57:45 -04'00'

(Signature) (Date)
Carl A. Newman
Other Transaction Agreement Officer, BARDA

FOR Regeneron Pharmaceuticals, Inc.

(b) (6)

3/21/2020

(Signature) (Date)
Robert E. Landry
Executive Vice President, Finance and Chief Financial Officer, Regeneron Pharmaceuticals, Inc.

END OF MODIFICATION No. 0006 TO HHSO100201700020C